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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,279	06/22/2001	Allan F. Willis	BAL-17-CON2 (BA-00136.2)	6271
7590	06/04/2004		EXAMINER	
STEPHEN E. BONDURA, ESQ. DORITY & MANNING, P.A. P.O. BOX 1449 GREENVILLE, SC 29602-1449			KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/887,279	WILLIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharon Kennedy	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06222001</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

***Specification***

The disclosure is objected to because of the following informalities: The specification should be updated at page 1, line 7 to include the patent number.

Appropriate correction is required.

***Double Patenting***

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,264,631. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application encompass the claims of the parent patent.

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,997,503. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application encompass the claims of the parent patent.

***Claim Rejections - 35 USC § 102***

Claims 1-2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mackin, US 4,976,710 with reference to Schiff, US 4,467,790, Hanson et al., US 4,402,307, Bolduc et al., Re.29,207, Saudagar, US 4,555,242.

Applicant's comments in the preliminary amendment have been carefully noted. Essentially, applicant argues that the gathers in the uninflated balloon make the device patentable. This is not convincing for the following reasons.

The stretch ability of a balloon on a balloon catheter can take several forms. The balloon can be elastic like a child's balloon and have an unlimited stretch ability until it bursts, or the balloon can have a set inflated size, the balloon being generally inelastic. In this second type, the balloon is typically folded over the catheter prior to insertion. This concept is so well known that it is rarely described in the patents unless the novel feature involves folding, the balloon polymer, etc. The reason why balloons are made with varying elasticities is dependent on the procedure performed. Generally inelastic balloons are formed on intra-arterial catheters so that the balloon has a controlled maximum diameter when fully inflated. The surgeon chooses the catheter to be used in a particular artery by balloon size. See Schiff, US 4,467,790, column 3, lines 40+ and Hanson et al., US 4,402,307, figures, column 3, lines 53-65. Both these patents show inelastic balloons. Other balloons have an expandability, which serves a function such as measuring the size of a uterine cavity, for example. See Buldoc et al., Re.29,207, column 2, lines 1-15 and Saudagar, US 4,555,242, column 3, line 66 and column 4, line 4, for example.

Mackin states that the balloon may comprise polyurethane. Polyurethane balloons can be elastic or generally inelastic, having a set inflation size. Mackin does not show a picture of the balloon in the unexpanded size, so it is difficult to ascertain whether the balloon has folds or gathers in the uninflated size.

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However, Mackin states that the balloon is "collapsible" (see abstract). Further, see Mackin, column 5, lines 15-20. The polyurethane balloon is described as collapsing on itself creating edges in the polyurethane. Although this is described as a problem with the balloon, clearly the polyurethane balloon is folded in the uninflated state, and not merely deflated as in Buldoc so that the balloon diameter size corresponds with the internal catheter diameter. In addition, "collapse" is a term of art which implies that the balloon folds in about itself instead of deflating to the diameter of the internal catheter. See Hanson column 3, lines 63-64.

In other words, the examiner takes the position that merely because Mackin does not specifically disclose a "gather" it does not mean that these are not inherently present when the balloon is not inflated.

In the alternative, the examiner takes the position that the claimed gathers set forth in the instant application are merely a design choice which have no functional significance. It is well known that the balloon on a balloon catheter can be either deflated to the size in the internal catheter or folded about itself. Applicant has not set forth any criticality which could make this feature patentable.

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sahota, US 5,160,321. See especially Figure 7 and the description thereof. Note that the Sahota thickened portions 34 correspond to the thickened portions forming applicant's rings. (Applicant states that rings 172,

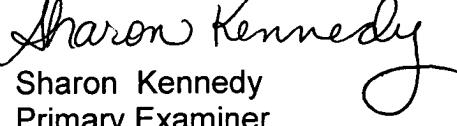
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172' and 172" are formed similar in production to rings 60-64, which are thickened portions.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 703/305-0154. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703/308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762